

**Environmental Assessment for Premarket Notification
(FCN No. 000051)**

1. Description of the Proposed Action

The proposed action is to provide for the safe use of phosphorus acid, bis[2,4-bis(1,1-dimethylethyl)-6-methylphenyl]ethyl ester (CAS Registry Number 145650-60-8) as a process stabilizer in olefin polymers:

- a. For use at levels not to exceed 0.5 percent by weight of olefin polymers complying with 21 CFR 177.1520(c). The finished polymers may only be used in contact with food types I, II, IV-B, VI-A, VI-B, VII-B and VIII identified in Table 1 of 21 CFR 176.170 (c), under condition of use A as described in Table 2 of 21 CFR 176.170(c).
- b. For use at levels not to exceed 0.1 percent by weight of high density ethylene polymers and copolymers complying with 21 CFR 177.1520(c), items 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, 3.6 (with a density not less than 0.94 gram per cubic centimeter) and item 5. The finished polymers may be used in contact with food types III, IV-A, V, VI-C, VII-A and IX identified in Table 1 of 21 CFR 176.170 (c), under condition of use B as described in Table 2 of 21 CFR 176.170(c). Provided, that the finished food contact articles have a volume of at least 18.9 liters (5 gallons).
- c. For use at levels greater than 0.01 percent by weight, but not to exceed 0.05 percent by weight, of ethylene polymers and copolymers complying with 21 CFR 177.1520(c), item 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, 3.4, 3.5, and 3.6 (where the density of each of these polymers is less than 0.94 gram per cubic centimeter). The finished polymers may be used in contact with food types III, IV-A, V, VI-C, VII-A and IX as described in Table 1 of 21 CFR 176.170 (c), under conditions of use B-H as described in Table 2 of 21 CFR 176.170(c).

This action was originally requested for Ciba Specialty Chemicals Corp, in food additive petition (FAP) 0B4702. The notice of filing, which contained the agency's decision that approval of the petition would qualify for a categorical exclusion under 21 *CFR* 25.32(i), was published in the *Federal Register* on January 12, 2000 (65 *FR* 1908). This exclusion is for actions for substances present in food-packaging material at not greater than 5 percent-by-weight and expected to remain with finished food-packaging material through use by

consumers or when the substance is a component of a coating of a finished food-packaging material.¹

The Food and Drug Administration Modernization Act (FDAMA) of 1997 (Pub. L. 105-115) amended section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) to establish a premarket notification (PMN) process as the primary method for authorizing new uses of food additives that are food contact substances. Section 409(h)(6) of the FFDCA defines a food contact substance (FCS) as any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food. Under the PMN process, a notification becomes effective 120 days after the date of receipt by FDA, unless FDA determines that, based on the data and information before the agency, the use of the substance is not safe and FDA objects to such notification within the 120-day period. If FDA does not object within 120 days to the use of an FCS that is the subject of a PMN, the substance may be legally marketed for the notified use.

In a letter dated October 26, 1999, the Agency told petitioners and requesters who had pending food additive petitions or threshold of regulation (TOR) exemption requests involving the use of an FCS, that the petitioned or requested action might be eligible for notification under section 409(h) of the FFDCA. The petitioners were told that they could consider withdrawing such petition or request and resubmitting it as a PMN. In a letter dated February 14, 2000, the petitioner's representative requested that FAP 0B4702 be converted to a PMN.

The types of substances and the uses of such substances under the categorical exclusion in 21 *CFR* 25.32(i) are the same whether a sponsor submits a food additive petition, a TOR exemption request, or a PMN. However, a categorical exclusion for allowing a PMN to become effective is not currently one of the enumerated types of actions listed in § 25.32(i). Therefore, we have prepared this Environmental Assessment for the subject notification.

2. Environmental Consequences of the Proposed Action

This action involves an FCS that is a minor component of finished food-packaging materials (<5% by weight of the finished packaging material) that remains with the packaging through

¹ This exclusion was promulgated in a final rule revising the agency's policies and procedures for implementing NEPA, published in the *Federal Register* on July 29, 1997 (62 *FR* 40570).

use by consumers. FDA has found that the very small quantities of substances that could potentially enter the environment from this type of use are highly unlikely to have a significant effect on the environment (61 *FR* 19476 at 19481-19482, May 1, 1996). The basis for FDA's decision to establish the categorical exclusion in § 25.32(i) for food additive petitions and TOR exemption requests is the same basis that would be applicable to PMNs. Therefore, FDA's experience with the food additive petitions that it reviewed to support a categorical exclusion for such actions is relevant to PMNs. The principal routes of environmental introduction of the types of substances included under § 25.32(i), whether reviewed in a food additive petition or in a PMN, result from their disposal in municipal solid waste combustors or landfills. These routes of disposal are governed by the regulations of the Environmental Protection Agency (EPA) in 40 *CFR* part 60 (combustors) and part 258 (landfills). Based on the low levels of use of these substances in packaging material, the introduction of combustion products or introductions at landfill sites are not environmentally significant. The petitioner states that the substance will be present in food packaging material at a level not greater than 0.5 percent-by-weight in olefin polymers and that it is expected to remain with the finished food-packaging material through use by consumers. Because of the nature of this type of action, we do not expect that any limited increase in environmental introductions resulting from this proposed action will threaten a violation of EPA's regulations governing combustors and landfills or have any other adverse environmental effects.

In the claim of categorical exclusion in FAP 0B4702, the petitioner stated that no extraordinary circumstance exists as per 21 *CFR* 25.21 which would cause an EA to be required. We do not believe that converting this petition to a PMN would alter the fact that no extraordinary circumstances are likely to occur as a result of this action.

3. Alternatives to the Proposed Action

Alternatives to the proposed action need not be considered, because no potential adverse environmental effects have been identified.

4. List of Preparers

Jeanette Glover Glew
Environmental Scientist
Chemistry and Environmental Review Team
Division of Product Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration